EPF's Response & Accompanying statement

Public consultation on the White Paper on Artificial Intelligence

14 June 2020

The European Patients' Forum (EPF) is an umbrella organisation of patients' organisations across Europe and across disease-areas. EPF represents the interests of over 150 million patients with chronic conditions across the EU who expect and rely on European cooperation to improve healthcare delivery and quality for all. In concert with its 75 members, EPF ensures the patient perspective in European key health debates, including digital health and health data. To achieve this goal, over the past few years EPF has been particularly active in these fields through both policy work[1] and several projects. [2]

This statement outlines EPF's response to the European Commission's White Paper on Artificial Intelligence consultation, submitted through the EU Consultation portal. The response and this statement have been developed in a consultative process together with our members and the EPF Digital Health Working Group. In this accompanying statement we will further explore some key elements, challenges and core issues related to the White Paper and to artificial intelligence (AI) in the field of health, that we deem crucial for the patient community.

Introduction

AI together with big data has the potential to transform several care delivery methods, and can provide great benefits at several levels of the healthcare value chain: improving population health, healthcare operations and healthcare-related innovation.[3] The 2020 EIT Health-McKinsey report "Transforming healthcare with AI – the impact on the workforce and organisations" highlights six areas where AI has a direct impact on the patient: self-care, prevention and wellness, triage and early diagnosis, diagnostics, clinical decision support, and care delivery in the context of chronic care management. AI can allow medical professionals to spend time on other activities, such as interacting with patients in a more meaningful way. AI-supported tools can also result in reduced costs, and support patients in taking control of their health. Furthermore, the COVID-19 crisis has shown how artificial intelligence can be an added value to the management of epidemics, and play an important role in diagnosis and modelling the spread of new cases.[4]

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[1] EPF policy and advocacy work related to digital health and data includes our position paper on eHealth (2016), GDPR guide for patients and patients' organisations (2016), Data and Artificial Intelligence EU Policy Briefing for Patient Organisations (2020), brief summary of our recent EPF survey on Electronic Healthcare Records (2020), EPF Response and accompanying statement - Public consultation on the European strategy on data (2020)

[2] EPF recent projects related to digital health and data include: Digital Health Europe, EHDEN – The European Health Data and Evidence Network, and Data Saves Lives.

[3] EIT Health – McKinsey & Company – Transforming healthcare with AI – The impact on the workforce and organisations (2020), https://www.mckinsey.com/~/media/McKinsey/Industries/Healthcare%20Systems%20and%20Services/Our%20Insights/Transforming%20healthcare%20with%20AI/Transforming-healthcare-with-AI.ashx

[4] McCall B. COVID-19 and artificial intelligence: protecting health-care workers and curbing the spread. Lancet Digital Health 2020 Apr; 2(4): e166–e167., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129544/

However, as with any new technology, there may also be unrealistic expectations. Artificial intelligence has risks, limitations and concerns including ethical, technical, and legal issues, which are often closely connected. AI depends on the availability of very large amounts of **good-quality data**. AI also risks making wrong decisions wrong decisions or lead to overdiagnosis, and **its reliability and safety** are particularly critical in healthcare, where errors can have serious consequences. Furthermore, lack of skills and health literacy, limited human autonomy and potential issues with access to AI solutions can also limit the potential of artificial intelligence in health.

The EU can set positive global standards when it comes to technological development in the AI field, but it must do so while ensuring inclusivity, trust, empowerment, and respect of everyone's fundamental rights. As stated in our **Manifesto for the 2019 European elections,** "the EU should ensure that Europe's future digital health tools and systems start from patients' priorities, and are co-developed with patients."[5]

EPF's recommendations

TOWARDS A EUROPEAN FRAMEWORK FOR TRUSTWORTHY, ETHICAL AND SAFE ARTIFICIAL INTELLIGENCE IN HEALTH

EPF welcomes the European Commission's White Paper on Artificial Intelligence and its approach based on excellence, trust, human rights, and fundamental values. The EU now has the chance to develop a strong AI framework that benefits people, businesses and governments, matching innovation with safety and trust. The EU can achieve this goal by **involving patient organisations as key stakeholders in shaping policy** to ensure trustworthy, ethical, safe, and inclusive artificial intelligence in healthcare.

1. Addressing the key challenges of AI in health

The application of AI in healthcare raises a series of concerns, in terms of ethics, safety and fundamental rights for citizens and patients.[6] The White Paper consultation addresses several crucial issues related to AI: it may endanger safety or lack accuracy; it may breach fundamental rights[7] and lead to discriminatory outcomes; it may take actions for which the rationale cannot be explained; it may make it more difficult for persons having suffered harm to obtain compensation. In our view, they must all be addressed with clarity and transparency to ensure safe and trustworthy AI in healthcare in Europe.

Ethicists have also identified a **risk on limiting human autonomy** in terms of a patient's right to free, fully-informed choice of, for example, treatment, if an AI system made a certain decision based on what it "thinks" is best for the patient.[8] Clearly, an important limitation and ethical implication of AI is that it does not possess all the human qualities that have a bearing on healthcare – which is fundamentally about human relationships. A specific concern in this regard is that artificial intelligence might be so good at picking up anomalies, for example in medical imaging such as X-rays and MRI

[5] EPF, Europe for Patients Manifesto,
[6] EPF, Data and Artificial Intelligence EU Policy Briefing for Patient Organisations
[7] Including human dignity, privacy, data protection, freedom of expression, workers' rights etc.
[8] EPF, Data and Artificial Intelligence EU Policy Briefing for Patient Organisations

scans, that it will end up **increasing overdiagnosis** and overtreatment. [9] Overdiagnosis by AI can increase the number of unnecessary medical interventions and – as any medical intervention carries potential risks – increase the risk of harming patients.[10] To limit these risks, AI's initial assessment should be complemented by regular human checks and monitoring needs to ensure unbiased and controlled processes.

Human oversight of the system and the decisions flowing from it should therefore remain central in healthcare, with AI as an important supporting tool. Furthermore, AI, if used to replace real human contact,[11] may actually increase social isolation cause the patient to get confused. [12]

Transparency and increased explainability[13] on how AI algorithms work and, when possible, on which data sets are used to test, train, and validate algorithms, are also fundamental to increase trust in artificial intelligence in healthcare.

EPF calls for particular attention in ensuring that AI in healthcare enhances society, and is an enabler of – and not a threat to – patients' rights and wellbeing, guaranteeing that the value of real human contact is not minimised or entirely replaced by technological alternatives.

2. Better data for safer and better AI

In addition to the ethical and human rights-related risks and challenges, harnessing the potential of AI in healthcare also raises important technical questions and concerns. The main one is the **dependency of AI on large amounts of good quality, unbiased, standardised, and interoperable data.** If the available data are not enough, not of good quality, inconsistent, or biased, this can strongly limit the potential of AI to be useful, accurate and safe and can lead to AI errors or overdiagnosis.

Biases in data also introduce ethical issues in terms of the potential for AI-enabled decisions themselves to be biased or discriminatory. Biases in data collection can affect the type of patterns AI will identify. This is an issue since, for example, specific population groups are often under-represented clinical trials and large data sets used to train AI. Bias in the data will have an effect on the algorithm that is developed, replicating the bias found in society.[14] Patients with multiple or rare diseases may also be affected by this.[15] Other issues need to be considered in using data for AI, such as fundamental rights, privacy and protection of personal data. There are risks for unwanted identification of individuals, for example based on their unique brain architecture – visible on MRI scans – or by using their genomic data. Improved and harmonised techniques of pseudonymisation

[9] Symptom checker apps present an interesting case, as "their recommendations might be overly cautious, potentially increasing demand for unnecessary tests and treatments.", Nuffield Council on Bioethics, Artificial intelligence (AI) in healthcare and research (2018), https://www.nuffieldbioethics.org/wp-content/uploads/Artificial-Intelligence-AI-in-healthcare-and-research.pdf

[10] https://www.theverge.com/2020/1/27/21080253/ai-cancer-diagnosis-dangers-mammography-google-paper-accuracy

[11] E.g. some systems called "social AI", such as virtual reality avatars, interact with humans by simulating human social characteristics.

[12] "Confusion "between humans and machines could have multiple consequences such as attachment, influence, or reduction of the value of being human. The development of human-like robots should therefore undergo careful ethical assessment." High-Level Expert Group on Artificial Intelligence, Ethics Guidelines for Trustworthy AI (2019), p.33, https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai,

[13] Guidelines of the High-Level Expert Group and the Communication on Building Trust in Human-Centric Artificial Intelligence, https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top

[14] Nuffield Council on Bioethics, Artificial intelligence (AI) in healthcare and research (2018)

[15] Treviranus J., Sidewalk Toronto and Why Smarter is Not Better (2018), https://medium.com/datadriveninvestor/sidewalk-toronto-and-why-smarter-is-not-better-b233058d01c8

and anonymisation play a central role to ensure data safety for AI, avoid data misuse and increase users' trust.[16]

Lack of **interoperability** and **standardisation** of data sets, such as electronic health record systems, is a major challenge. Sometimes traditional analytical methods outperform machine learning, or the addition of AI does not improve results.[17] As with any scientific endeavour, correct use of AI hinges on whether the correct scientific question is being asked, and whether one has the right high-quality data to answer that question. As machine learning is based on patterns in big data, the system is only as good as the data that is fed to it.

Availability of well-annotated and appropriately-pseudonymised clinical data is also fundamental for AI **research and innovation projects**. Data access and data sharing, crucial to the success of these projects, can be a significant bottleneck, incurring long delays in their execution as well as substantial legal and administrative costs. Difficulties in executing data access and data sharing agreements are further compounded when public and private sector priorities clash. Any actions to enhance **secure, but rapid access to valuable research and innovation datasets** would surely enhance the quality of AI research and innovation at European level.

Finally, the importance of data for AI clearly connects the future frameworks and initiatives on artificial intelligence and healthcare to the upcoming EU work on the **European Health Data Space**, which EPF also commented on via its dedicated public consultation.[18] The EU strategy on AI should also be aligned with and take into account relevant initiatives and projects on data, such as the EMA strategy on big data.[19] Furthermore, the EU should explore coordination on data standards at international level, increasing shared knowledge on quality and interoperability beyond EU borders.

3. Developing an ecosystem of excellence for AI in healthcare

The White Paper includes six key actions deemed fundamental in building an ecosystem of excellence that can support the development and uptake of AI across the EU economy: working with Member States; focussing the efforts of the research and innovation community; skills development; focus on SMEs; partnership with the private sector and promoting the adoption of AI by the public sector.

EPF agrees that the six actions are all key in building excellence in AI at European level, but we also emphasise their strong interdependency and need to be adapted to address the uniqueness of AI in healthcare. These actions will have to be tailored to take into consideration the specific challenges of healthcare and to ensure inclusion of the patient perspective in research, development of policy frameworks, and implementation of innovative solutions.

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[16] EPF, EPF Response and accompanying statement - Public consultation on the European strategy on data, 2020, https://www.eu-patient.eu/globalassets/library/data-strategy-consultation-response---epf-statement_finalversion.pdf

[17] Austin PC, Tu JV, Lee DS, Logistic regression had superior performance compared with regression trees for predicting in-hospital mortality in patients hospitalized with heart failure, J Clin Epidemiol. 2010 Oct;63(10):1145-55. doi: 10.1016/j.jclinepi.2009.12.004. Epub 2010 Mar 21.https://www.ncbi.nlm.nih.gov/pubmed/20304609

[18] EPF, EPF Response and accompanying statement - Public consultation on the European strategy on data, 2020

[19] HMA-EMA Joint Big Data Taskforce Phase II report: 'Evolving Data-Driven Regulation' and key recommendations, (2019) https://www.ema.europa.eu/en/documents/other/hma-ema-joint-big-data-taskforce-phase-ii-report-evolving-data-driven-regulation_en.pdf; https://www.ema.europa.eu/en/documents/other/priority-recommendations-hma-ema-joint-big-data-task-force_en.pdf

The efficiency of the proposed actions will be compromised without collaboration across sectors, and in the absence of meaningful citizen and patient involvement at all levels. To reinforce this point, **EPF calls the European Commission to ensure the involvement of citizens, patients and other relevant stakeholders** – healthcare professionals, in particular – as the **seventh key action to achieve a European ecosystem of excellence for AI in healthcare**.

4. Transparent, effective, and sustainable AI research and innovation

Creating an ecosystem of excellence for research on AI in Europe is key, and all the actions mentioned in the White Paper – support the establishment of a world-class research hub, connect research excellence and set up a public-private partnership for industrial research – are surely important. When it comes to healthcare-specific public-private partnerships for industrial research in the AI field, they should be driven by public interest and their results should contribute to public health and wellbeing. If it is true that innovative solutions often require collaboration between multiple stakeholders, there must be clear priority-setting criteria based on potential impact on unmet health needs, and any entanglements between these priorities and other interests must be avoided. Innovative products and services developed with EU funding must be, at the end of the day, accessible and affordable to those who can benefit from them, be it individual patients or health systems.

Innovation[20] in AI, as in others, should be valued for its potential to improve the quality of care and of life, over and above mere potential for putting a product on the market.

EPF would also like to emphasise the importance of **sustainability** in the context of research and innovation. Investment in this field should also include funding to ensure the sustainability of high-value assets developed by past and present initiatives, on which future innovation can be built. For health research and innovation projects, ensuring the sustainability of clinical assets would recognise the valuable contributions patients make to these projects, sacrificing their time and, in some cases, exposing themselves to risks. A sustainable ecosystem of excellence for research on AI should therefore aim to guarantee access to data and assets in the post-project period.

AI should also be used to develop solutions for **health inequalities**, including addressing social determinants of health, but also increasing equitable access to high-quality healthcare for all, in line with the fundamental shared values of European health systems.

Finally, to strengthen AI research and innovation there is a need for accurate risk assessments that identify the probability and magnitude of potential harms. Consequently, efforts should also be directed towards ensuring that, where required, AI research and innovation projects undergo ethics review, by panels that possess the necessary AI and data science expertise.

5. Improve European coordination on AI

Improved coordination at European level will be key to advance together on AI while limiting inequalities and harmonising innovation and accessibility to AI-related benefits for patients.

The EU should also promote the uptake of AI by businesses and the public sector but possibly adopting different approaches, such as specific regulation and standards for the business sector, and enhanced support and coordination for the public sector (e.g. capacity building and of course ad-hoc regulation

[20] EPF calls for a wide definition of innovation that includes people-focused, social, organisational and systems innovation. Research into the design of health and social care and how care is delivered, can add significant value in providing evidence for targeting resources efficiently, thus contributing to the sustainability of health systems.

and standards). EPF welcomes the priority given to the healthcare sector in the White Paper when it comes to the adoption of AI by the public sector.

Given the importance of data for artificial intelligence, addressing AI will be fundamental when discussing the European Health Data Space (EHDS). As mentioned in our response to the Data Strategy consultation[21] and considering the peculiarity of the health sector and its specific challenges and risks, a sector-specific approach on healthcare and data is needed. However, the development of the EHDS must include the **necessary mechanisms, such as governance structures and appropriate capacity-building, to ensure the meaningful involvement of patients from the very beginning**, in order to shape a framework that benefits from the unique experience and knowledge of patients and provides benefits for society.

Ethical AI governance systems are another area where policy alignment and inter-state coordination are essential, and enhanced cooperation at European level should also look at ensuring equitable access and avoid exacerbation of health inequalities within and across Member States.

6. Boost skills and digital health literacy as a precondition to exploit AI at European level

Health literacy is a key component of patient empowerment[22] and a major priority for patients.[23] **Enhancing digital health literacy and data literacy levels is crucial to increase patients' knowledge and trust on AI in health and enable them to better understand and exercise their rights while realising the societal benefits of AI innovation in healthcare**. Education and health literacy for the public, and for patients specifically, can also increase civil society's capacity to be engaged in developing policy and practice on AI, especially in healthcare.

EPF welcomes the importance given to skills and literacy in the White Paper and stresses the need for active patient' involvement in shaping future skills, educational and training policies for AI and health. We would like to emphasise that health literacy is not only about the skills of individuals, but a relational concept that requires healthcare professionals, organisations and systems to become more easily understandable and navigable to all individuals, whatever their health literacy levels. Health literacy – including digital and data literacy – is therefore an important strategy for health equity and to avoid exacerbation of the digital divide.[24]

Considering the rapid speed of innovation in the AI sector, EPF calls for particular attention to developing skills, health literacy and dedicated education and training for citizens, patients and healthcare professionals, through dedicated resources and initiatives both at European and National level. Also, considering that AI is clearly a constantly evolving sector, it will be crucial to address skills, literacy, education, and training with a dynamic and equally evolving approach. In doing so, healthcare professionals will be able to be up to date with innovation in the field, use AI safely and efficiently, but

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[21] EPF, EPF Response and accompanying statement - Public consultation on the European strategy on data, 2020

[22] EMPATHiE Project, https://www.eu-patient.eu/whatwedo/Projects/completed-projects/EMPATHiE/

[23] EPF, Charter on Patient Empowerment (2016), https://www.eu-patient.eu/whatwedo/campaign/PatientsprescribE/charter-on-patient-empowerment/; EPF, Campaign on Patient Empowerment: Roadmap for Action (2017), https://www.eu-patient.eu/whatwedo/campaign/PatientsprescribE/roadmap-for-action/;
EPF, Europe for Patients Manifesto (2019), https://www.europeforpatients.eu/

[24] Roediger A et al. (2019) "Nothing about me without me: why an EU health literacy strategy embracing the role of citizens and patients is needed", Archives of Public Health vol.77, no: 17. https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-019-0342-4; EPF, Consensus paper: Making health literacy a priority for in EU policy, https://www.eu-patient.eu/globalassets/policy/healthliteracy/health-literacy-consensus-paper_2016.pdf

also adequately interact with patients and citizens. Informed patients and citizens, might therefore feel more confident and ready to harness the potential of artificial intelligence and better engage with the underlying digital ecosystem (e.g. data sharing).

7. Defining 'risk' for AI applications in healthcare

The White Paper defines high-risk applications based on two-levels risk-based approach, identifying two key cumulative criteria: sector of employment of AI and use of AI applications. While healthcare is clearly acknowledged as one of the ''high-risk'' sectors, the Paper also highlights that 'softer' application of AI in healthcare, for example AI-driven appointment scheduling system in a hospital, would not be necessarily flagged as ''high-risk''.

In general terms, the adoption of new and specific rules addressing specific risks related to the application of AI in healthcare should surely be considered. However, especially for AI applications in the healthcare sector, whether the introduction of new compulsory requirements should be limited to high-risk applications depends on how the future EU rules on AI will detail the risk-based approach and therefore the list of high-risk applications uses. Indeed, although the White Paper already clearly considers healthcare to be a 'high-risk' sector of application (first principle), AI in healthcare has a series of particular risks that require a thoroughly developed sector-based approach to clearly define what should be considered a 'high-risk use' (second principle).

EPF calls **for particular attention on the definition of high-risk AI in healthcare and a dedicated discussion on this topic inclusive of the views of patients**. Since the EU approach to define high-risk will be linked to more restrictive or relaxed assessment procedures, it will be necessary to carefully evaluate what could be considered to be low-risk AI application in healthcare. This should be done not only taking into consideration obvious risks, such as inaccurate diagnosis or prognosis and incorrect treatments,[25] but also indirect or secondary negative impacts on the life of the patients such as unwanted identification of individuals,[26] even minimal delays of care, [27] reduced freedom of choice, social isolation or distress. When addressing the balance between potential benefits and potential harms, the balance should always be on the benefits side.

8. Establish assessment mechanisms for safe and ethical AI in healthcare

High-Risk AI applications in healthcare should be subject to strict assessments procedures, harmonised at EU level, to fully ensure patient' safety and address ethical questions. In EPF's view, the best solution would be a **combination of ex-ante compliance and ex-post enforcement mechanisms, with the important specification that ex-ante compliance should be assessed by an independent body**. These mechanisms, which should include an ethics review, should be transparent, and in the case of healthcare applications, should include end users – patients – as contributors to the assessment procedure, where possible.

[25] As mentioned in our briefing paper on big data and artificial intelligence, AI might be so good at picking up anomalies, for example in medical imaging such as x-rays and MRI scans, that it will end up increasing overdiagnosis and overtreatment. Symptom checker apps also present an interesting case as their recommendations might be overly cautious, potentially increasing demand for unnecessary tests and treatments.

[26] There are for examples risks for unwanted identification of individuals, for example based on their unique brain architecture – visible on MRI scans – or by using their genomic data.

[27] For example, due to malfunctioning in AI-led systems of hospital management

It is crucial to ensure that the assessment mechanisms ensure safety and effectiveness of AI systems as they are used and enable prompt action if problems arise during their lifetime. This is particularly important for AI, considering that machine learning systems adjust themselves as they "learn".

As concerns the proposal of a **voluntary labelling system** for non-high-risk applications, such an approach could indeed be useful to facilitate the identification of trustworthy applications for both patients and professionals. As previously mentioned, however, the key question here is how to define high-risk and non high-risk applications. We would like to see meaningful and inclusive involvement of end users in the development of labelling systems, to ensure that labelling systems are easily interpretable and tailored to the specific needs of the end user group.

9. A fit-for-purpose regulatory framework to increase trust on AI

AI-specific risks, safety and liability, when it comes to healthcare in particular, should be addressed specifically in EU legislation, avoiding duplication with existing regulatory frameworks (from data protection to medical devices) while ensuring adequate protection for individuals. **EPF calls for inclusion of patients' views from the very beginning in the process of adaptation and update of the current legislation or, where necessary, the development of new legislation**. In addition, given the speed of technological advancement in this field, any new AI-related legislative framework should incorporate requirements for systems to be re-evaluated, and for the new legislation to be adapted, in a rapid and nimble way in response to technological evolution – thereby **'future-proofing'** the legislation.

Furthermore, we believe that any new legislation should be founded on solid ethical principles and recommendations, for example those recently outlined by AI4People and in the Asilomar AI Principles, developed in consultation with all relevant stakeholders – including the individuals that the principles are designed to protect. Respect of these AI-specific, foundational ethical principles should be ensured via expert ethical review of AI applications, particularly in the field of health.

Ethical risks and potential harms of AI should be carefully considered to provide more legal certainty, particularly for healthcare products and for products that make use of personal data. Clarity and transparency on liability and responsibility, therefore on who should respond to potential harm caused by AI applications, will be also crucial to increase trust in AI. People should always have effective and transparent mechanisms for redress.

In general terms, on top of ensuring ample protection and safety, the exercise of rights defined by EU legislation should be made simple and not overly burdensome.